

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No: 10/776,337
Filed: February 12, 2004
First Named Inventor: Changquan Sun
Docket: PC28117A
Confirmation N.: 1777
Examiner: Michael P Barker
Art Unit: 1626
For: Polymorphs of pyrrole substituted 2-indolinone protein kinase
inhibitors
Dated: January 14, 2009

COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, VA 22313-1450

REQUEST FOR RECONSIDERATION OF PATENT TERM
ADJUSTMENT UNDER 37 CFR §1.705(d)

Sir:

U.S. Patent 7,452,913 has been granted a patent term adjustment of 517 days. For reasons set forth below Applicants request a patent term adjustment of 1051 days. The issue in this case is the method of calculating the patent term adjustment to be granted to a patent based upon the Patent Office failure to grant the patent within 3 years from the filing date.

Under the recent decision of the U.S. District Court for the District of Columbia (Wyeth et al. v. Jon W. Dudas) (September 30, 2008) the patent term adjustment is the sum of prosecution delays attributable to USPTO and the delay in issuing the patent beyond the three years from the filing date, less any period of actual calendar overlap between the prosecution delays and the issuance delay. In addition, Applicants' delay and certain other periods set forth in 35 U.S.C. § 1.54(b) are also excluded. In the present case, there were Applicants' delays of 128 days.

There are two periods of USPTO delay in the present case. The first period begins 14 months after the filing date, that is, on April 12, 2005. This delay period ended on

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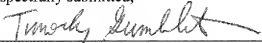
September 28, 2006, when the USPTO mailed a restriction election of species requirement. This first period is 534 days of USPTO delay.

The second period of delay began three years after the filing date of this application, that is, on February 12, 2004. This delay continued until the issuance of the patent on November 18, 2008. This period is 645 days of USPTO delay. Since there is no overlap between the prosecution delays and the delay in issuance, Applicants are entitled to a patent term adjustment equal to the sum of the two USPTO delay periods minus the Applicants' delays, that is, a patent term adjustment of 1051 days.

Included herewith is a detailed calendar of the patent term adjustment for this patent. This patent is not subject to a terminal disclaimer.

Applicants believe that pursuant to 37 CFR 1.18(e), a \$200.00 processing fee is due in connection with this application for patent term adjustment. Please charge the required fee(s) to Deposit Account No. 16-1445. Thank you for your consideration.

Respectfully submitted,



Timothy J. Gumbleton, Patent Agent
Registration No. 54,143

Date: January 14, 2009

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AIPA Term Calculation Report

| APPLICATION INFORMATION | | | |
|-------------------------|--|---------------------------|------------------|
| Docket Number: | PC28117A | User Name: | Beenges, Cynthia |
| Application Number: | 10/776,337 | Firm/Company Name: | Pfizer, Inc. |
| Filing Date: | 02/12/2004 | User Comments: | |
| Title Invention(s): | POLYMORPHIS OF PYRROLE SUBSTITUTED 2-INDOLINONE PROTEIN KINASE INHIBITORS, Changquan Sun, Portage, MI (US) | | |
| | Calculation Generated: | 12/11/2008 10:40:47 AM ET | |

| AIPA TERM CALCULATION SUMMARY | |
|--|--------------------|
| Earliest Referenced Application under 35 USC § 120, 121, or 365(c): | 02 / 12 / 2004 |
| Filing Date (US National Application): | 02 / 12 / 2004 |
| Net Adjustment (Credits): | 1179 Days |
| Net Adjustment Debits: | 128 Days |
| Patent Term Adjustment: | 1051 Days |
| AIPA Patent Term End Date: | 12 / 29 / 2026 (1) |
| (1) Assurance paid of all maintenance fees, no intervening acts, and no 35 USC 156 regulatory extensions. Terminal disclaimer(s) filed in this case, if any, may result in an earlier term end date. Without adjustment, the term would end on 07/12/2024. | |

FILE # A113 ACTION SUMMARY (2)

| Event | Date Received | Related Event | Date Issued (Month/Day/Year) | Date (Month/Day/Year) | Credit (Days/Hours) |
|---|---|--|---------------------------------|--------------------------|------------------------|
| <p>02/12/2004 Filing Date under 35 USC 111(a) (US National Application)</p> | <p>14-Month PTO First Action</p> <p>PTO must mail a notification under 35 USC 132 or a notice of allowance under 35 USC 151 not later than 14 months after the date on which the application was filed under 35 USC 111(a) or fulfilled the requirements of 35 USC 371 in an international application. Period of adjustment (credits) begins on the day after the date that is 14 months after the date on which the application was filed under 35 USC 111(a) or fulfilled the requirements of 35 USC 371 and ending on the date of mailing of either an action under 35 USC 132, or a notice of allowance under 35 USC 151, whichever occurs first. 35 USC 154(b)(1)(A)(i); 37 CFR 1.702(a)(1), 1.703(a)(1).</p> | <p><i>First PTO Action:</i> 09/28/2006 Restriction/ Election-of-Species</p> | | | 514 |
| <p>02/12/2004 Filing Date under 35 USC 111(a) (US National Application)</p> | <p>3-Year PTO Issue of Patent</p> <p>PTO must issue a patent within 3 years (not including exclusions) after the date on which the application was filed under 35 USC 111(a) or the national stage commenced under 35 USC 371(b) or (i) in an international application. Period of adjustment (credits) begins on the day after the date that is 3 years after the date on which the application was filed under 35 U.S.C. 111(a) or the national stage commenced under 35 USC 371(b) or (i) in an international application and ending on the date a patent was issued, but not including the sum of the listed exclusionary periods. 35 USC 154(b)(1)(B); 37 CFR 1.702(b), 1.703(b).</p> <p>You have elected to analyze this rule without applying the USPTO 37 CFR § 1.703(f) Actual Delay Limitation in determining Credit Days under this rule. This is consistent with DC District Court ruling in Wyeth et al. v. Dudas, No. 07-1492 (D.D.C. September 30, 2008).</p> | <p><i>Issue Date:</i> 11/18/2008 Issue Date</p> | | | 645 |
| <p>05/13/2004 Notice to File Missing Parts (nonprovisional application)</p> | <p>3-Month Applicant Response to Notice or Action</p> <p>Period of adjustment (credits) shall be reduced for the period in excess of 3 months taken to reply to any PTO notice or action making any rejection, objection, argument, or other request, beginning on the day after the date that is 3 months after the date of mailing or transmission of the Office communication and ending on the date the reply was filed. The period, or shortened statutory period, for reply set in the action or notice has no effect on this deadline. 35 USC 154 (b)(2)(C)(ii); 37 CFR 1.704(b).</p> <p>Where applicant shows, in spite of all due care, applicant was unable to respond within the 3-month period, all or part of adjustment may be reinstated for up to 3 additional months. 35 USC 154(b)(3)(C); 37 CFR 1.705(c).</p> <p>You have indicated that no 1.705(c) Showing of Due Care was made.</p> | <p><i>Applicant Response:</i> 08/12/2004 Filing Fee Payment (Original or Supplemental)</p> | | 0 | |

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| <p>D</p> <p>09/28/2006 Restriction / Election-of-Species</p> | <p>3-Month Applicant Response to Notice or Action</p> <p>Period of adjustment (credits) shall be reduced for the period in excess of 3 months taken to reply to any PTO notice or action making any rejection, objection, argument, or other request, beginning on the day after the date that is 3 months after the date of mailing or transmission of the Office communication and ending on the date the reply was filed. The period, or shortened statutory period, for reply set in the action or notice has no effect on this deadline. 35 USC 154 (b)(2)(C)(ii); 37 CFR 1.704(b).</p> <p>Where applicant shows, in spite of all due care, applicant was unable to respond within the 3-month period, all or part of adjustment may be reinstated for up to 3 additional months. 35 USC 154(b)(3)(C); 37 CFR 1.705(G).</p> <p>You have indicated that no 1.705(G) Showing of Due Care was made.</p> | <p><i>Applicant Response:</i></p> <p>10/26/2006 Response to Election-of-Species / Restriction Filed</p> | <p>0</p> | |
| <p>10/26/2006 Response to Election-of-Species / Restriction Filed</p> | <p>4-Month PTO Response to Applicant Reply</p> <p>PTO must respond to a reply under 35 USC 132 not later than 4 months after the date on which the reply was filed. The period of adjustment (credits) begins on the day after the date that is 4 months after the date a reply under 37 CFR 1.111 or in compliance with 37 CFR 1.113(e) was filed and ending on the mailing date of either an action under 35 USC 132, or a notice of allowance under 35 USC 151, whichever occurs first. 35 USC 154(b)(1)(A)(ii); 37 CFR 1.702(a)(2), 1.703(a)(2)(3).</p> <p>Reply Having Omission</p> <p>Period of adjustment (credits) shall be reduced where applicant submits a reply having an omission (37 CFR 1.135(c)), for the period beginning on the day after the date the reply having an omission was filed and ending on the date that the reply or other paper correcting the omission was filed. 37 CFR 1.704(G)(7).</p> <p>The USPTO interprets this rule as not limited to Office actions under 37 CFR 1.135(c), but it applies when the Office issues any action or notice indicating that a reply has an omission which must be corrected. See AFEP 2732 at 2700-20 (8th ed., rev. 2, May 2004).</p> | <p><i>PTO Response:</i></p> <p>11/07/2006 Notice of Informal or Non-Responsive Amendment</p> | <p>0</p> | |
| <p>10/26/2006 Informal or Non-Responsive Amendment after Examiner Action</p> | <p>3-Month Applicant Response to Notice or Action</p> <p>Period of adjustment (credits) shall be reduced for the period in excess of 3 months taken to reply to any PTO notice or action making any rejection, objection, argument, or other request, beginning on the day after the date that is 3 months after the date of mailing or transmission of the Office communication and ending on the date the reply was filed. The period, or shortened statutory period, for reply set in the action or notice has no effect on this deadline. 35 USC 154 (b)(2)(C)(ii); 37 CFR 1.704(b).</p> <p>Where applicant shows, in spite of all due care, applicant was unable to respond within the 3-month period, all or part of adjustment may be reinstated for up to 3 additional months. 35 USC 154(b)(3)(C); 37 CFR 1.705(G).</p> <p>You have indicated that no 1.705(G) Showing of Due Care was made.</p> | <p><i>Reply/Other Paper Correcting Omission:</i></p> <p>12/07/2006 Response to Election-of-Species / Restriction Filed</p> | <p>42</p> | |
| <p>11/07/2006 Notice of Informal or Non-Responsive Amendment</p> | <p>Applicant Response:</p> <p>12/07/2006 Response to Election-of-Species / Restriction Filed</p> | <p>0</p> | | |

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| 1 | 12/07/2006 Response to Election-of-Species/ Restoration Filed | PTO must respond to a reply under 35 USC 132 not later than 4 months after the date on which the reply was filed. The period of adjustment (credits) begins on the day after the date that is 4 months after the date a reply under 37 CFR 1.111 or in compliance with 37 CFR 1.113(e) was filed and ending on the mailing date of either an action under 35 USC 132, or a notice of allowance under 35 USC 151, whichever occurs first. 35 USC 154(b)(1)(A)(iii); 37 CFR 1.702(a)(2), 1.703(a)(2)(3). | <i>PTO Response:</i> 01/23/2007 Non-final Action | | 0 |
| 1 | 01/23/2007 Non-final Action | Period of adjustment (credits) shall be reduced for the period in excess of 3 months taken to reply to any PTO notice or action making any rejection, objection, argument, or other request, beginning on the day after the date that is 3 months after the date of mailing or transmission of the Office communication and ending on the date the reply was filed. The period, or shortened statutory period, for reply set in the action or notice has no effect on this deadline. 35 USC 154 (b)(2)(C)(ii); 37 CFR 1.704(b). Where applicant shows, in spite of all due care, applicant was unable to respond within the 3-month period, all or part of adjustment may be reinstated for up to 3 additional months. 35 USC 154(b)(3)(C); 37 CFR 1.705(g). You have indicated that no 1.705(g) Showing of Due Care was made. | <i>Applicant Response:</i> 07/18/2007 Reply after Non-final Action under 37 CFR 1.111 | 86 | |
| 1 | 07/18/2007 Reply after Non-final Action under 37 CFR 1.111 | PTO must respond to a reply under 35 USC 132 not later than 4 months after the date on which the reply was filed. The period of adjustment (credits) begins on the day after the date that is 4 months after the date a reply under 37 CFR 1.111 or in compliance with 37 CFR 1.113(e) was filed and ending on the mailing date of either an action under 35 USC 132, or a notice of allowance under 35 USC 151, whichever occurs first. 35 USC 154(b)(1)(A)(iii); 37 CFR 1.702(a)(2), 1.703(a)(2)(3). | <i>PTO Response:</i> 09/24/2007 Restoration/ Election-of-Species | | 0 |
| 1 | 09/24/2007 Restoration/ Election-of-Species | 3-Month Applicant Response to Notice or Action Period of adjustment (credits) shall be reduced for the period in excess of 3 months taken to reply to any PTO notice or action making any rejection, objection, argument, or other request, beginning on the day after the date that is 3 months after the date of mailing or transmission of the Office communication and ending on the date the reply was filed. The period, or shortened statutory period, for reply set in the action or notice has no effect on this deadline. 35 USC 154 (b)(2)(C)(ii); 37 CFR 1.704(b). Where applicant shows, in spite of all due care, applicant was unable to respond within the 3-month period, all or part of adjustment may be reinstated for up to 3 additional months. 35 USC 154(b)(3)(C); 37 CFR 1.705(g). You have indicated that no 1.705(g) Showing of Due Care was made. | <i>Applicant Response:</i> 11/01/2007 Response to Election-of-Species/ Restoration Filed | 0 | |

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| <p>1</p> <p>Response to Election-of-Species/ Restriction Filed</p> <p>11/01/2007</p> | <p>4-Month PTO Response to Applicant Reply</p> <p>PTO must respond to a reply under 35 USC 132 not later than 4 months after the date on which the reply was filed. The period of adjustment (credits) begins on the day after the date that is 4 months after the date a reply under 37 CFR 1.111 or in compliance with 37 CFR 1.113(e) was filed and ending on the mailing date of either an action under 35 USC 132, or a notice of allowance under 35 USC 151, whichever occurs first. 35 USC 154(b)(1)(A)(iii); 37 CFR 1.702(a)(2)(3), 1.703(a)(2)(3).</p> | <p><i>PTO Response</i></p> <p>12/20/2007</p> <p>Non-final Action</p> | | | |
| <p>4</p> <p>Non-final Action</p> <p>12/20/2007</p> | <p>3-Month Applicant Response to Notice or Action</p> <p>Period of adjustment (credits) shall be reduced for the period in excess of 3 months taken to reply to any PTO notice or action making any rejection, objection, argument, or other request, beginning on the day after the date that is 3 months after the date of mailing or transmission of the Office communication and ending on the date the reply was filed. The period, or shortened statutory period, for reply set in the action or notice has no effect on this deadline. 35 USC 154 (b)(2)(C)(ii); 37 CFR 1.704(b).</p> <p>Where applicant shows, in spite of all due care, applicant was unable to respond within the 3-month period, all or part of adjustment may be reinstated for up to 3 additional months. 35 USC 154(b)(3)(C); 37 CFR 1.705(e).</p> <p>You have indicated that no 1.705(e) Showing of Due Care was made.</p> | <p><i>Applicant Response</i></p> <p>03/20/2008</p> <p>Reply after Non-final Action under 37 CFR 1.111</p> | | | |
| <p>4</p> <p>Reply after Non-final Action under 37 CFR 1.111</p> <p>03/20/2008</p> | <p>4-Month PTO Response to Applicant Reply</p> <p>PTO must respond to a reply under 35 USC 132 not later than 4 months after the date on which the reply was filed. The period of adjustment (credits) begins on the day after the date that is 4 months after the date a reply under 37 CFR 1.111 or in compliance with 37 CFR 1.113(e) was filed and ending on the mailing date of either an action under 35 USC 132, or a notice of allowance under 35 USC 151, whichever occurs first. 35 USC 154(b)(1)(A)(iii); 37 CFR 1.702(a)(2)(3), 1.703(a)(2)(3).</p> | <p><i>PTO Response</i></p> <p>07/10/2008</p> <p>Notice of Allowance under 35 USC 151</p> | | | |
| <p>0</p> <p>Notice of Allowance under 35 USC 151</p> <p>07/10/2008</p> | <p>3-Month Applicant Response to Notice or Action</p> <p>Period of adjustment (credits) shall be reduced for the period in excess of 3 months taken to reply to any PTO notice or action making any rejection, objection, argument, or other request, beginning on the day after the date that is 3 months after the date of mailing or transmission of the Office communication and ending on the date the reply was filed. The period, or shortened statutory period, for reply set in the action or notice has no effect on this deadline. 35 USC 154 (b)(2)(C)(ii); 37 CFR 1.704(b).</p> <p>Where applicant shows, in spite of all due care, applicant was unable to respond within the 3-month period, all or part of adjustment may be reinstated for up to 3 additional months. 35 USC 154(b)(3)(C); 37 CFR 1.705(e).</p> <p>You have indicated that no 1.705(e) Showing of Due Care was made.</p> | <p><i>Applicant Response</i></p> <p>10/10/2008</p> <p>Issue Fee Payment under 35 USC 151</p> | | | |

4. Month PTO Issue of Patent

| 10/10/2008 Issue Fee Payment under 35 USC 151 | PTO must issue a patent not later than 4 months after the date on which the issue fee was paid under 35 USC 151 and all outstanding requirements were satisfied. The period of adjustment (credits) begins on the day after the date that is 4 months after the date the issue fee was paid and all outstanding requirements were satisfied and ends on the day the patent issues. 35 USC 154(b)(1)(A)(iv); 37 CFR 1.702(a)(4); 1.703(a)(6) | Issue Date: 11/18/2008 Issue Date | | |
|---|---|---|-----|------|
| Total Exclusion, Debt, and Credit Days: | | 0 | 128 | 1179 |
| Overlap Days (6) : | | 0 | 0 | 0 |
| Net Exclusion, Debt, and Credit Days: | | 0 | 128 | 1179 |
| Patent Term Adjustment Days (7) : | | | | 1051 |

- (2) Calculations of Debt, Credit, and Exclusion Days are determined by the rule assignments, assignments of related events, and analysis options in the Apply Term Rules tab. The patent practitioner using this system is responsible for reviewing and updating the Apply Term Rules tab to ensure all data is complete, correct, and consistent with their judgment and interpretation of applicable legal authority.
- (3) Exclusion Days are periods which are not included in determining the end of the 3-year period after the date on which the application was filed under 35 USC 111(a), or the national stage, commenced under 35 USC 371(b) or (f) in an international application, used to determine credits under the 3-year PTO Issue of Patent rule. See 43 CFR 1540(b)(1)(B)(i)-(iii); 37 CFR 1.703(b)(1)-(5); 1.703(b)(1)-(4).
- (4) Debt Days are days where grounds for reduction of period of adjustment of patent term exist. See, e.g., 37 CFR 1.704. Debt Days are sometimes referred to as Applicant Delay.
- (5) Credit Days are days where grounds for adjustment of patent term exist. See, e.g., 37 CFR 1.702, 1.703. Credit Days are sometimes referred to as USPTO Delay.
- (6) To the extent credit periods overlap other credit periods, debt periods overlap other debt periods, or exclusion periods overlap other exclusion periods, overlaps are subtracted so that each calendar day generates at most one credit day, one debt day, and one exclusion day.
- (7) Patent Term Adjustment Days equals Net Credit Days minus Net Debt Days, but is not less than zero.